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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

CHRISTOPHER A. ROWLAND, MICHAEL G. VERGANO, BRYAN P. EDDY, and PETER B. COTTON,

Junior Party
(Applicant 09/154,834),

v.

GEORGE W. WEAVER, HAROLD JACOB, DAVID F. LEIGHTON, and DAMOND C. HOLSINGER,

Senior Party
(Patents 5,788,681 and 5,843,028).

Patent Interference No. 104,515

Before LEE, GARDNER-LANE and MEDLEY, Administrative Patent Judges.

MEDLEY, Administrative Patent Judge.

FINAL DECISION AND JUDGMENT UNDER 37 CFR § 1.658(a)

A. Introduction

This is a decision on priority between junior party Rowland and senior party Weaver. A final hearing was held 10 May 2002.

B. Findings of facts

The following findings of fact as well as those contained elsewhere in this opinion are supported by a preponderance of the evidence.

1. Rowland is involved on the basis of application 09/154,834, filed 17 September 1998.

2. Weaver is involved on the basis of U.S. Patent 5,788,681, granted 4 August 1998, based on application 08/730,343, filed 15 October 1996 and U.S. Patent 5,843,028, granted 1 December 1998, based on application 08/706,311, filed 30 August 1996.

3. Rowland has been accorded benefit for the purpose of priority of U.S. application 08/842,210, filed 23 April 1997, U.S. application 08/648,356, filed 14 May 1996, and U.S. application 08/242,168, filed 13 May 1994.

4. Weaver has been accorded benefit for the purpose of priority of U.S. application 08/189,317, filed 31 January 1994 for both of its involved patents.

5. The interfering subject matter pertains to a three-lumen catheter or a method for using a three-lumen catheter, having one lumen for a guide wire, one lumen for contrasting fluid, and one lumen for an electrosurgical instrument.

6. Count 2[1], the sole count of the interference is as follows:

Count 2

A method according to any of claims 98, 105, 112, 119, or 120 of the Rowland application,

or

an apparatus according to any of claims 90, 92, 97, 118, or 125 of the Rowland application,

or

a method according to any of claims 7, 11, or 15 of the Weaver '028 patent,

or

an apparatus according to any of claims 16, 18, or 23 of the Weaver '681 patent.

7. Rowland seeks to establish priority with respect to any one of Rowland's apparatus claims 90, 92, 97, 118 or 125 (Paper 96 at 20). Those claims are as follows:

90. A catheter for advancement through the accessory channel of an endoscope into a body passage within the gastrointestinal system, said catheter comprising:

a substantially cylindrical, flexible catheter body having a substantially uniform outer diameter extending throughout its length;

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[1] Count 2 was substituted for the original count 1. (Paper 64).

said catheter body having a proximal end and a distal tip and at least three independent lumens extending lengthwise thereof, each said lumen having an entry port at the proximal end thereof and at least a first lumen and a second lumen of said at least three independent lumens having axially facing exit ports disposed in said distal tip, the first lumen being configured for receiving a wire guide and the second lumen being configured for injection of contrast fluid, and

wherein a third lumen of the at least three lumens has an electrosurgical instrument configured to form a sphincterotome/papillotome disposed therein.

92. A catheter assembly for advancement and manipulation through the accessory channel of an endoscope into a body passage within the gastrointestinal system, the catheter assembly comprising:

an elongate catheter body having a proximal end and a distal end;

a first elongate lumen extending from the proximal end to the distal end of the catheter body, the first elongate lumen configured for receiving a guide wire and having an entry port at the proximal end of the catheter body and an exit port the distal end of the catheter body;

a second elongate lumen extending from the proximal end to the distal end of the catheter body, the second elongate lumen being configured for injection of tracer dye out the distal end of the elongate catheter body, such that tracer dye may be released from the distal end of the elongate catheter body while a guide wire is disposed in the first lumen; and

a third elongate lumen extending from the proximal end of the catheter body toward the distal end of the catheter body, the third lumen having an electrosurgical tissue cutting instrument disposed therein.

97. A catheter assembly for advancement and manipulation through the accessory channel of an endoscope into a body passage, the catheter assembly comprising:

an elongate catheter body having a proximal end and a distal end having a distal tip;

first, second and third lumens formed within the catheter body, each of the first, second and third lumens extending from respective ports formed adjacent the proximal end and toward the distal end, the first and the second lumens terminating in ports at the distal tip; and

an electrosurgical tissue cutting instrument disposed in the third lumen for selectively cutting tissue, the tissue cutting instrument forming a papillotome/sphincterotome.

118. Catheter assembly for advancement and manipulation through an endoscope into a body passage comprising;

(a) an elongate catheter body having first, second and third lumens formed within said catheter body, said first lumen configured for receiving a guide wire and said second lumen configured for injecting contrast agent, said first and second lumens terminating in ports at the distal end of said catheter body; and

(b) an electrosurgical tissue cutting instrument disposed in said third lumen.

125. Catheter assembly for advancement and manipulation through an endoscope into a body passage comprising:

(a) an elongate catheter body having first, second and third lumens formed within said catheter body, said first and second lumens terminating in ports at the distal end of said catheter body; and

(b) an electrosurgical tissue cutting instrument disposed in said third lumen.

8. The claims of the parties are:

Rowland:	90-125
Weaver '681:	1-23
Weaver '028:	1-17

9. The claims of the parties that are designated as corresponding to Count 2[2] are:

Rowland:	90-125
Weaver '681:	16-23
Weaver '028:	7-17

9. The claims of the parties that are designated as not corresponding to Count 2[3] are:

Rowland:	none
Weaver '681:	1-15
Weaver '028:	1-6

Rowland's brief on priority

10. Rowland alleges a date of conception of 13 May 1991 (Paper 96 at 16).

11. Rowland alleges a date of actual reduction to practice of the count of 11 October 1991 (Paper 96 at 16).

12. Rowland alternatively argues a date of actual reduction to practice of the count of 8 February 1994, when a three-lumen catheter was actually used in a human (Paper 96 at 17).

13. For its 8 February 1994 reduction to practice date, Rowland alleges acts of diligence toward actually reducing the count to practice, from prior to Weaver's 31 January 1994 benefit date until 8 February 1994 (Paper 96 at 17).

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[2] See Paper 64.

[3] See Paper 64.

Conception

14. Inventors Rowland and Vergano testified that on or about 13 May 1991, they arrived at the idea of a three-lumen catheter, where one of the lumens was for a guide wire, one for injecting contrast fluid and one for containing a cutting wire (RR 290, ¶ 3).

15. Bryan Eddy allegedly made a sketch showing the cross section and dimensions of the three-lumen catheter conceived by Vergano and Rowland, whereby an engineering drawing was completed on 14 June 1991 (RR 011, ¶ 7).

16. The engineering drawing does not show or describe the elements of the count (Rowland Ex. 2013).

Actual reduction to practice

17. By October 11, 1991, inventors Eddy and Vergano and lab technician Heidi Bell (Bell), created prototypes of the three-lumen catheter (RR 007, ¶ 12; 012, ¶ 9; and 016, ¶ 7).

18. Eddy, Vergano and Bell all testified that the three-lumen catheter prototypes were as depicted in Figs. 1, 2, 4 and 9 of U.S. Patent 5,547,469[4], and includes a three-lumen catheter body 11 having a lumen 17 for contrast fluid, a lumen 20 for a cutting wire and a lumen 16 for a guide wire (Fig. 2), with

[4] U.S. patent 5,547,469 (application 08/242,168) is the parent case of Rowland's involved application, for which Rowland has been accorded benefit (Finding 3).

lumens 16 and 17 having ports 14 and 65 at the distal end of the catheter (Fig. 9) (RR 007, ¶ 12; 012, ¶ 9; and 016, ¶ 7).

19. Inventors Eddy and Vergano and noninventor Bell testified that there was no need for testing in a human of the three-lumen catheter device, since they believed that the three-lumen catheter device (three-lumen Sphincterotome) could be used in the same manner as a commercially available two-lumen catheter device (two-lumen Ultratome) (RR 007, ¶ 12; 012, ¶ 9; and 017, ¶ 9).

20. Although they believed that testing in a human was not necessary, Eddy, Vergano, and Bell did "test" the three-lumen catheter by (1) confirming that the tips of the catheter were articulated and oriented in the same way as the tips of the two-lumen catheter; and (2) cutting pieces of raw cow liver to confirm that the cutting wire could cut through tissue in the same manner as a cutting tool used in the two-lumen catheter (RR 007, ¶ 12; 012, ¶ 9; and 017, ¶ 9).

21. Rowland alternatively argues that if actual use in humans is required to establish an actual reduction to practice, then such testing was performed on 8 February 1994 (Paper 96 at 22).

22. Rowland alleges that it sent three-lumen catheter devices to physicians for their evaluation, and that one of these devices went to Dr. David Carr-Locke at Brigham and Women's

Hospital in Boston.

23. Christopher A. Rowland testified that on 10 January 1994, various physicians were requested to evaluate the Ultratome XL and that on 8 February 1994, Dr. David Carr-Locke used the Ultratome XL on a patient and completed the evaluation form (RR 026).

24. In further support of its allegation that various physicians received the Ultratome XL for their evaluation, Rowland submits into evidence a letter dated January 10, 1994 to Dr. Bohorfoush of Milwaukee, Wisconsin (Rowland Ex. 2032).

25. The letter refers to the Ultratome XL and describes the device as improving cutting wire orientation and allowing the user to inject contrast fluid in a separate injection lumen.

26. The letter states that the product is confidential and for Dr. Bohorfoush's evaluation only.

27. In support of its assertion that Dr. Carr-Locke used the three-lumen catheter in a patient on 8 February 1994, Rowland submits into evidence exhibit 2033, which is entitled "Ultratome XL Evaluation."

28. Inventors Vergano and Rowland testified that "Ultratome XL" was the name given the three-lumen catheter made by the Rowland inventors (RR 008, ¶ 15; and 026).

Weaver's case on priority

29. Weaver relies on its 31 January 1994 benefit date.

30. In its brief, Weaver alleges that Rowland abandoned, suppressed or concealed its October 1991 reduction to practice.

31. Weaver timely filed a notice of intent to argue abandonment, suppression, or concealment by Rowland (Paper 76).

C. Discussion

Rowland's Case on Priority

Rowland, as the junior party in this interference, has the burden of establishing priority with respect to Weaver by a preponderance of the evidence. 37 CFR § 1.657(b).

Priority of invention belongs to the first party to reduce the invention to practice unless the other party can establish that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing the invention to practice. Eaton v. Evans, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000). Here, Rowland alleges a conception date of 13 May 1991 and an actual reduction to practice date of 11 October 1991.

Alternatively, Rowland argues that it reduced the invention to practice on 8 February 1994 and that it was diligent from a time just prior to Weaver's 31 January 1994 benefit date until its 8 February 1994 reduction to practice.

Weaver argues that Rowland has failed to prove a date of conception prior to its January 31, 1994 filing date. Weaver argues that none of Rowland's declarants compare the elements of the count with the elements of the proofs (Paper 102). We disagree. Rowland has proved conception by at least 11 October 1991. At that time, the inventors built a prototype of the three-lumen catheter. Inventors Vergano and Eddy testified to this, along with noninventor Bell, who assisted in building the prototypes (Finding 17).

Vergano, Eddy and Bell testified in detail that the prototypes built were as shown in Rowland's parent patent which shows the elements of a three-lumen catheter having a lumen for a cutting instrument, a lumen for contrasting fluid, and a lumen for a guide wire (Finding 18). The figures that the declarants direct us to show three separate lumens as recited in the count. Weaver does not challenge the inventors' or Ms. Bell's testimony. Weaver did not cross-examine any of the Rowland declarants. Thus, Rowland has established a prior conception by 11 October 1991.

"In order to establish an actual reduction to practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations of the interference count; and (2) he determined that the invention would work for its intended purpose." Cooper v. Goldfarb, 154

F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). An inventor must prove these elements by a preponderance of the evidence. Id.

Weaver argues that Rowland has not met the first prong of the Copper test, since Rowland has not introduced into evidence the prototypes allegedly made by Vergano and Bell by 11 October 1991 (Paper 102 at 12). Weaver's argument is misplaced. It is not necessary for Rowland to introduce into evidence the prototypes. Rowland has submitted testimonial evidence of inventors Vergano and Eddy and non-inventor Bell. As stated above in connection with conception of the invention, Vergano, Eddy and Bell testified as to the structure of the prototypes, and that the structure meets every element of the count (Finding 18). Accordingly, Rowland has met the first prong of the Cooper test. Weaver has failed to sufficiently demonstrate otherwise.

In order to determine if Rowland has met the second prong of the Cooper test, we must first determine the intended purpose of the subject matter of the count. Each of the apparatus claims that constitute the count require a catheter for advancement through an endoscope and into a body passage. Each of the method claims that constitute the count requires positioning or threading the catheter into a body passage. The purpose of inserting the catheter into the body passage is to inject contrast fluid, and/or to cut tissue. Thus, the intended purpose

of the subject matter of the count is to insert the catheter into a body passage for performing some operation in the body passage. Rowland did not test the three-lumen catheter to ensure that it could be inserted into a body passage, or to ensure that tissue can be cut and contrast fluid can be injected in the body passage.

Rowland argues that testing in humans was not necessary, since inventors Eddy and Vergano and noninventor Bell believed that the three-lumen catheter device would be used, and would work in the same manner as the two-lumen catheter device (Finding 19). Instead the inventors, along with Ms. Bell, performed a bench test to confirm that the tips of the three-lumen catheter were oriented in the same fashion as in the two-lumen catheter, and that the cutting tool would work the same as a cutting tool in a two-lumen catheter (Finding 20).

The problem with Rowland's argument is that Rowland simply asks us to take the inventors' and Ms. Bell's word that the three-lumen catheter device was so similar to the two-lumen catheter device that testing in humans was not necessary. Rowland fails to direct us to evidence to support the assertion. Obviously, the two devices are not the same. Yet, Rowland provides no adequate explanation as to why testing of the three-lumen catheter in a body passage was not necessary despite the three-lumen catheter's being a different device from the two-

lumen catheter. The bench testing and cutting of cow liver do not demonstrate to the trier of fact that the three-lumen catheter device would work for its intended purpose, e.g., that it would work in a body passage, or that the three-lumen catheter device was so similar to the two-lumen catheter device that testing of the three-lumen catheter device in a body passage was not necessary.

Rowland cites to case law for the proposition that for simple devices testing is not necessary. However, based on this record we do not know that the three-lumen catheter device is so simple that testing is not required. Rowland has not submitted evidence sufficient to demonstrate that the three-lumen catheter is so simple in construction and operation that no testing is required in light of the knowledge that a two-lumen catheter works. Argument of counsel cannot take the place of evidence lacking in the record. Estee Lauder Inc. v. L'Oreal, S.A., 129 F.3d 588, 595, 44 USPQ2d 1610, 1615 (Fed. Cir. 1997).

For these reasons, Rowland has failed to demonstrate by a preponderance of the evidence that it reduced the invention of the count to practice by 11 October 1991 as alleged.

Alternatively, even if Rowland's 11 October 1991 activities do amount to a reduction to practice, Rowland has failed to negate the inference that it did suppress or conceal its invention.

A party may not rely on an actual reduction to practice if the invention was subsequently suppressed or concealed. 35 U.S.C. § 102(g). Mere delay alone will not establish suppression or concealment. Young v. Dworkin, 489 F.2d 1277, 1281, 180 USPQ 388, 391-2 (CCPA 1974). However, an intent to suppress or conceal may be inferred from an unreasonable lapse of time between the actual and constructive reductions to practice. Peeler v. Miller, 535 F.2d 647, 653, 190 USPQ 117, 122 (CCPA 1976). The inference can be negated, e.g., by disclosing the invention to the public (Palmer v. Dudzik, 481 F.2d 1377, 1386, 178 USPQ 608, 615 (CCPA 1973)); or by improving or perfecting the invention within a reasonable time after the reduction to practice, and disclosing that improvement in an application promptly filed thereafter (see Horwath v. Lee, 564 F.2d 948, 950, 195 USPQ 701, 704 (CCPA 1977)).

What constitutes an unreasonable lapse of time must be determined on a case-by-case basis. In Shindelar v. Holdeman, 628 F.2d 1337, 207 USPQ 112 (CCPA 1980), the CCPA found a 29 month delay between an actual reduction to practice and a constructive reduction to practice to be an unreasonable length of time. To negate the inference, the junior party in Shindelar had presented evidence of some activity during the 29 month period. The CCPA, however was not persuaded that such activity excused the delay and thus agreed with the board that the junior

party suppressed or concealed the invention. Id. 628 F.2d at 1342-3, 207 USPQ at 116-7.

In its principal brief, Weaver argues that Rowland abandoned, suppressed or concealed its invention. Specifically, Weaver argues that if Rowland's activities in October 1991 amounted to a reduction to practice of the invention of the count, then Rowland's delay until May 1994, to file an application created an inference that Rowland suppressed the invention, thus requiring Rowland to demonstrate otherwise (Paper 101 at 7). Weaver recognizes that Rowland submitted, in connection with its priority case, evidence showing activities that occurred after Rowland's October 1991 reduction to practice. However, Weaver argues that the activities were towards improving the product, in which event the improvements were not demonstrated to be part of Rowland's May 1994 application. Then by law, Weaver argues, Rowland's acts of improvement cannot justify the delay towards filing Rowland's application (Paper 101 at 9).

Rowland argues that Weaver has not demonstrated that Rowland suppressed or concealed the invention, since Weaver ignored Rowland's evidence. We disagree. There is an inference of suppression or concealment when there is an unreasonably long lapse of time between the actual reduction to practice and the filing of the application. Here, the 31 months between the 11

October 1991 alleged date of reduction to practice and the 13 May 1994 filing of the Rowland application is unreasonably long. Thus, an inference exists. That inference, however, is rebuttable.

In its opposition, Rowland fails to address Weaver's argument that the activities performed between October 1991 and May 1994 were towards improving the three-lumen device and that such improvements were not made part of the Rowland application. Inventor Vergano testified that he continued working with Mr. Eddy and Ms. Bell to improve the three-lumen sphincterotome (RR 007, ¶ 13). The activities that Rowland discusses in its opposition to Weaver's brief relate to continuous efforts to improve the three-lumen catheter.

Rowland's activities include the following: (1) in February 1992 the inventors seek to improve the quality of tubing; (2) a meeting is held in October 1992 to discuss design problems of trifurcation, skiving the irrigation port, paint adhesion and the quality of the tubing; (3) in November 1992, there is a discussion of tip orientation problems; (4) also in November 1992, a plan for development and launch of the three-lumen catheter was discussed; (5) in June of 1993, Rowland sought advice regarding the type of regulatory approval required for the three-lumen catheter; (6) in July 1993 schedules were set for tooling completion, documentation completion, testing completion

and release to production; (7) in September 1993 assignment of product numbers were made; (8) in November 1993 Rowland distributed a memo regarding the Ultratome XL project which addressed launch target date, assigning a product name, printing and packaging details and samples required for applications; (9) testing on the orientation of the tips of the three lumen catheter is ongoing; (10) 18 November 1993 - the first four lots of the Ultratome XL are built on the production floor, and at the same time, there is a concern related to wall thicknesses of the three-lumen catheter; (11) January 10, 1994 market evaluation period begins (Paper 108 at 17-19).

Thus, as demonstrated from the above Rowland was continuously improving the three-lumen catheter during the 31 months. The inventors were continuously testing and improving the three-lumen catheter in order to overcome problems with tip orientation, quality of tubing, trifurcation, skiving irrigation ports, paint adhesion, and wall thickness of the tubing. Yet, Rowland fails to demonstrate that the improvements made were part of its application.

The other activities that Rowland directs us to reflect Rowland's efforts to commercialize the "improved" three-lumen catheter device, such as establishing a plan for developing and launching the three-lumen catheter, seeking regulatory approval, assigning a product name, printing and packaging of the product,

marketing the product, and evaluating marketing efforts. Rowland's commercialization activities will not save the day for Rowland. Furthermore, most of the commercialization activities occurred after the improvements and perfections were made. Such events occurring near the end of the 31 months do not justify the delay prior to those events.

It is well established that when "the delay [of filing an application] is caused by working on refinements and improvements which are not reflected in the final patent application, the delay will not be excused." Lutzker v. Plet, 843 F.2d 1364, 1367, 6 USPQ2d 1370, 1372 (Fed. Cir. 1988). Furthermore, "when the activities which cause the delay go to commercialization of the invention, the delay will not be excused." Id.

Here, Rowland makes no effort to direct us to where in its application the improvements are described, despite Rowland's being on notice from Weaver of that requirement. We decline to search through Rowland's application to determine if the noted improvements are described in Rowland's application. Rowland should have done that in response to Weaver's charge that the activities were all towards improving the three-lumen catheter and would not excuse a delay in filing its application.

Rowland alternatively argues that the Rowland inventor's resumption of activities prior to Weaver's entering the field, negates a charge of suppression and concealment, citing to Paulik

v. Rizkalla, 760 F.2d 1270, 1273, 226 USPQ 224, 225-226 (Fed. Cir. 1985). Rowland argues that it resumed activity when it sent three-lumen catheters to various doctors for evaluation and that it was diligent towards actually reducing the invention to practice by 8 February 1994 (Paper 108 at 20). For the reasons given infra, we are not persuaded that Rowland has demonstrated an 8 February 1994 reduction to practice or diligence prior to Weaver's entry into the field until 8 February 1994.

Rowland lastly argues that it publicly disclosed its invention, thereby negating a charge that Rowland suppressed its invention from the public. Rowland argues that the public acquired the benefit of its invention when it sent three-lumen catheters to various doctors prior to Weaver's entrance into the field (Paper 108 at 20). Rowland alleges that it sent three-lumen catheter devices, along with a letter explaining the features of the device to various doctors. However, insufficient evidence supports that assertion. Inventor Rowland's testimony that the various three-lumen devices were sent to various doctors is not sufficiently corroborated. The letter to Dr. Bohorfoush, that Rowland apparently relies on as an example of the type of letter sent to the various doctors, does not demonstrate that several letters and three-lumen catheter devices were sent to various physicians. Furthermore, the letter to Dr. Bohorfoush indicates that the enclosed product is "CONFIDENTIAL and for your

market evaluation only" (Rowland Exhibit 2032). Thus, the letter suggests that the features of the product were not to be disclosed to the general public.

For the reasons stated above, Rowland suppressed or concealed its invention, assuming that it had actually reduced the invention to practice by 11 October 1991.

Rowland's alternative argument that it reduced the invention to practice on 8 February 1994

Assuming that the 11 October 1991 activities establish only a prior conception and not an actual reduction to practice, Rowland must demonstrate that it actually reduced the invention to practice on 8 February 1994 and that it was diligent from a time just prior to Weaver's 31 January 1994 benefit date until its 8 February 1994 reduction to practice date.

Rowland submits that on or about January 10, 1994, Rowland sent three-lumen Ultratome XL devices to physicians for their evaluation, that one went to Dr. Carr-Locke at Brigham and Women's Hospital in Boston, and that Dr. Carr-Locke used the device in a patient on 8 February 1994 (Paper 96 at 23). In support of this assertion, Rowland directs us to its exhibits 2032 and 2033.[5]

[5] Rowland's brief refers to "RR 29" - record page 29. However, no page 29 was ever submitted by Rowland. During oral argument, counsel for Rowland indicated that the references to "RR 29" were typographical errors and that the references to "RR 29" should be replaced with references to Ex. 2033 (Transcript at 81). After the hearing, Rowland submitted a "revised brief" to

Exhibit 2032 is a letter dated 10 January 1994 to Dr. Anthony Bohorfoush, M.D. of Froedtert Memorial in Milwaukee, Wisconsin from Chris Rowland. Exhibit 2033 is entitled "Ultratome XL™ Evaluation" and appears to be an evaluation form of an "Ultratome XL."

Apparently, Rowland submits the letter and the evaluation form as proof of the truth of the matter asserted. No one testified as to what the letter or the evaluation form represent. Thus, Rowland is relying on the exhibits themselves to support the truth of the assertion. In that light, the letter and evaluation form should not be considered, since both are inadmissible hearsay. For these reasons alone, Rowland has failed to sufficiently demonstrate by a preponderance of the evidence that it reduced the invention of the count to practice on 8 February 1994.

Alternatively, we have considered the letter and evaluation form in support of Rowland's argument. However, for reasons discussed below, we are not persuaded that the letter and/or the evaluation form demonstrate that the subject matter of the count was actually reduced to practice.

It is not clear from the evaluation form that the device

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clarify the replacement of references to "RR 29" with "Ex. 2033" (Paper 124). However, that brief will not and has not been considered, since Rowland has made alterations beyond deleting references to "RR 29" to the last two pages, contrary to its statement that the brief is identical to its original.

evaluated was the same as the device of the subject matter of the count, or that the device evaluated was used in a patient. On the evaluation form, there is no description of the elements of the count. However, the evaluation form is entitled "Ultratome XL™ Evaluation", and two of the Rowland inventors testified that the three-lumen catheter sphincterotome device (that was conceived) was given the name Ultratome XL (Finding 29). Thus, it would appear that Rowland has sufficiently demonstrated that the evaluation form was for evaluating the subject matter of the count. However, the Rowland inventors were working on at least one other three-lumen catheter, known as the balloonotome. The Rowland inventors were working on both the balloonotome catheter and the sphincterotome catheter at the same time. Initially, the project of developing the three-lumen balloonotome catheter and the three-lumen sphincterotome catheter were referred to as the "Balloonotome Project" (RR 005, ¶ 7). It is not apparent then that only the three-lumen sphincterotome was given the name "Ultratome XL." Furthermore, there is no corroborating evidence that the name Ultratome XL meant the device defined by the count. Rowland has submitted only the inventor's testimony in that respect.

Lastly, there is nothing on the evaluation form that indicates that the apparatus as defined by the count was actually tested for its intended purpose, e.g., to be inserted in a body

passage and to perform cutting and visualizing. The evaluation form merely asks the reader questions about the "Ultratome XL." None of the questions or responses to the questions indicate affirmatively that the device was actually used in a patient. The questions and answers could easily apply to evaluating the product outside of a patient, or what the evaluator believed without actually using the device on a patient.

For all of the above reasons, Rowland has failed to sufficiently demonstrate, by a preponderance of the evidence, that it reduced the invention to practice on 8 February 1994.

Although Rowland has failed to prove an actual reduction to practice on 8 February 1994, we will address Rowland's argument that it was diligent from a time prior to Weaver's effective filing date until Rowland's alleged 8 February 1994 reduction to practice date. In that respect, Rowland has failed to sufficiently demonstrate that it was diligent.

The date of activity that Rowland relies on that is prior to Weaver's 31 January 1994 effective filing date is 10 January 1994. At that time, a letter was sent to Dr. Bohorfoush requesting that he evaluate the "Ultratome XL" (Rowland Ex. 2032). As stated above, the letter is hearsay and should not be considered. Even considering the document, Rowland has failed to account for the time between the 10 January 1994 letter and 8 February 1994.

Rowland argues that by 30 January 1994, physicians had received the three-lumen catheter device and that between January 30, 1994 and February 8, 1994, one of the physicians, Dr. Carr-Locke, evaluated each patient to determine if he could use the device (Paper 96 at 23). However, Rowland fails to direct us to evidence that supports this assertion. We do not know that physicians received the three-lumen device by 30 January 1994. We further do not know that Dr. Carr-Locke evaluated patients to determine if the three-lumen catheter could be used on a particular patient. Rowland relies on attorney argument alone in support of its assertions. As stated above, argument of counsel cannot take the place of evidence lacking in the record.

Accordingly, Rowland has failed to demonstrate that it was diligent from a time prior to Weaver's 31 January 1994 effective filing date until its 8 February 1994 reduction to practice.

Weaver's motion to suppress Rowland's exhibits

Weaver seeks to suppress the following Rowland exhibits from consideration: RX2033, RX2035, RX2036, and RX2037.

Weaver failed to attach its objections to its motion to suppress Rowland's evidence (See Paper 1 at § 48). Accordingly, the motion is dismissed on that grounds alone.

Nonetheless, we will consider Weaver's motion on the merits. We find it unnecessary to consider the specific objections to the admissibility of Rowland's exhibits 2035, 2036 and 2037, since

Rowland has failed to demonstrate priority by a preponderance of the evidence even assuming Rowland's exhibits 2035, 2036 and 2037 to be admissible.

We agree with Weaver that Rowland exhibit 2033 should be excluded. As discussed above in connection with Rowland's case on priority, the exhibit is relied on for the truth of the matter asserted. The exhibit is an evaluation form submitted by Rowland to prove that Dr. Carr-Locke tested and evaluated the subject matter of the count in a patient. There is no declaration of one testifying as to what the evaluation shows or describes. Rowland relies on the exhibit as demonstrating the truth that the testing and evaluating were actually performed.

Rowland argues that exhibit 2033 is a record of a regularly conducted activity (Paper 11 at 5). However, Rowland fails to provide evidence of this in the form of a declaration of one that can testify that the exhibit is indeed a record of a regularly conducted activity. For this reason, we grant Weaver's motion to exclude Rowland exhibit 2033. Rowland is not prejudiced by our decision, since we alternatively consider the exhibit 2033 as discussed supra.

Accordingly, Weaver's motion with respect to RX2035, RX2036, and RX2037 is dismissed as moot. Weaver's motion with respect to RX2033 is granted.

Rowland's motion to suppress Weaver's evidence

Rowland seeks to suppress Weaver exhibits 1017 and 1018. Rowland failed to attach its objections to its motion to suppress Weaver's evidence (See Paper 1 at § 48). Accordingly, the motion is dismissed on that grounds alone.

Even considering Rowland's motion on the merits, the motion is dismissed as follows. We find it unnecessary to consider the specific objections to the admissibility of Weaver's exhibits 1017 and 1018, since those exhibits were not considered in rendering our opinion. Weaver relied on exhibits 1017 and 1018 in support of its argument that Rowland did not actually reduce the invention to practice by 11 October 1991. Since Rowland failed to demonstrate by a preponderance of the evidence that it had reduced the invention to practice by 11 October 1991, there was no occasion for us to consider Weaver's argument, and thus Weaver exhibits 1017 and 1018.

Accordingly, Rowland's motion with respect to Weaver exhibits 1017 and 1018 is dismissed as moot.

D. Judgment

Based on our decision, it is

ORDERED that judgment as to Count 2 (Paper 64), the sole count in the interference, is awarded against junior party CHRISTOPHER A. ROWLAND, MICHAEL G. VERGANO, BRYAN P. EDDY, and PETER B. COTTON.

FURTHER ORDERED that junior party CHRISTOPHER A. ROWLAND, MICHAEL G. VERGANO, BRYAN P. EDDY, and PETER B. COTTON is not entitled to a patent containing claims 90-125 (corresponding to Count 2) of application 09/154,834;

FURTHER ORDERED that a copy of this paper shall be made of record in the files of application 09/154,834, and U.S. Patent 5,788,681 and U.S. Patent 5,843,028;

FURTHER ORDERED that if there is a settlement agreement, attention is directed to 35 U.S.C. § 135(c) and 37 CFR § 1.661.

JAMESON LEE
Administrative Patent Judge

SALLY GARDNER-LANE
Administrative Patent Judge

SALLY C. MEDLEY
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

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